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| 7278 | 7590 | 01/02/2008 | EXAMINER | |
| DARBY & DARBY P.C. | | | CHONG, YONG SOO | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/644,577

Applicant(s)

SANCHEZ ET AL.

Examiner

Yong S. Chong

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/12/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

Claim(s) 1-19 have been cancelled. Claim(s) 20-38 are pending and examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and modified below.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-31, 38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-9 of copending Application No. 11/625,554 in view of Applicant's own admission of the prior art.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter is directed to treating premenstrual syndrome in a patient who failed to respond to initial treatment with a selective serotonin reuptake inhibitor (SSRI) other than escitalopram comprising administering an effective amount of escitalopram.

The referenced claims disclose a method of treating premenstrual dysphoric disorder, which overlaps in scope with premenstrual syndrome, since symptoms such as depression, anxiety, panic attacks, breast tenderness or swelling, headaches, joint or muscle pain, bloating, and weight gain are commonly associated with both syndromes. The referenced claims also disclose administering escitalopram in the same dosage range; however, do not teach a patient population who has failed to respond to initial treatment with a SSRI other than escitalopram.

In applicant's own admission, the specification discloses that clinical studies on depression and anxiety disorders indicate that non-response or resistance to SSRIs, where at least 40-60% reduction in symptoms has not been achieved during the first 6 weeks of treatment (pg. 1, paragraph 3).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to administer escitalopram to a

patient who failed to respond to the initial treatment with a selective serotonin reuptake inhibitor other than escitalopram.

A person of ordinary skill in the art would have been motivated to administer escitalopram to a patient who failed to respond to the initial treatment with a selective serotonin reuptake inhibitor other than escitalopram because: (1) SSRIs are known to be useful in the treatment of premenstrual syndrome and premenstrual dysphoric disorder; (2) escitalopram is a well known SSRI; and (3) clinical studies on depression and anxiety disorders indicate that non-response or resistance to SSRIs, where at least 40-60% reduction in symptoms has not been achieved during the first 6 weeks of treatment. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating a patient who failed to respond to the initial treatment with a selective serotonin reuptake inhibitor other than escitalopram by administering an effective amount of escitalopram as an alternative source of a SSRI.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Examiner thanks Applicant for pointing out that Application 10/984,536 has been abandoned in favor of a continuing Application 11/625,554. Applicant's request to hold this rejection in abeyance until the conflicting claims have been deemed allowable has been acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20-38 are rejected under 35 U.S.C. 103(a) as being obvious over Boegesoe et al. (US Patent 4,943,590) and further in view of Norden et al. (US Patent 5,789,449), the Merck Manual (16th edition, 1992, pg. 1791), and Applicant's own admission of the prior art.

The instant claims are directed to a method of treating premenstrual syndrome by administering escitalopram to a patient who failed to respond to an initial treatment of a SSRI other than escitalopram.

Boegesoe et al. discloses the method of treating depression in a patient with the (+) enantiomeric form of citalopram, otherwise referred to as escitalopram (col. 1, lines 9-26), which is also disclosed to be an inhibitor of serotonin uptake. It was discovered

that almost the entire serotonin reuptake inhibition resided in the (+)-citalopram enantiomer or escitalopram (col. 2, lines 38-40). Acceptable pharmaceutical salts of escitalopram include oxalate (col. 1, lines 29-42) in addition to the crystalline form (example 2). The daily dosage of escitalopram is disclosed to be from 5 to 50 mg (col. 8, lines 55-60).

However, Boegesoe et al. fail to disclose specifically a method of treating premenstrual syndrome with escitalopram to a patient who failed to respond to an initial treatment of a SSRI other than escitalopram.

Norden et al. teach a method of treating premenstrual syndrome by administering a serotonin reuptake inhibitor, for example citalopram, which is the racemic form of escitalopram, to a patient (col. 18, lines 36-38).

Moreover, the Merck Manual teaches that depression is a symptom of premenstrual syndrome (16th edition, 1992, pg. 1791).

In applicant's own admission, the specification discloses that clinical studies on depression and anxiety disorders indicate that non-response or resistance to SSRIs, where at least 40-60% reduction in symptoms has not been achieved during the first 6 weeks of treatment (pg. 1, paragraph 3).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to administer escitalopram to a patient suffering from premenstrual syndrome who failed to respond to an initial treatment of a SSRI other than escitalopram.

A person of ordinary skill in the art would have been motivated to administer escitalopram to a patient suffering from premenstrual syndrome who failed to respond to an initial treatment of a SSRI other than escitalopram because: (1) Norden et al. teaches that premenstrual syndrome can be treated by a SSRI, for example the racemic form of escitalopram; (2) Boegesoe et al. teach that escitalopram is a SSRI, which is useful for the treatment of depression; (3) Boegesoe et al. also teach that almost the entire serotonin reuptake inhibition resided in the (+)-citalopram enantiomer or escitalopram, therefore providing a more effective form of the drug; (4) Merck Manual teaches that depression is a symptom of premenstrual syndrome; and (5) clinical studies on depression and anxiety disorders indicate that non-response or resistance to SSRIs, where at least 40-60% reduction in symptoms has not been achieved during the first 6 weeks of treatment. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating a patient suffering from premenstrual syndrome who failed to respond to an initial treatment of a SSRI other than escitalopram by administering an effective amount of escitalopram since the skilled artisan would have turned to another SSRI, known to treat the same disorder.

Response to Arguments

Applicant argues that the cited references would not have motivated one of ordinary skill in the art to administer escitalopram for the treatment of PMS in patients who have failed to respond to treatment with an initial, non-escitalopram SSRI. Specifically, one of ordinary skill in the art would have had no reasonable expectation

that a patient would be responsive to another member of the same drug class, especially if they have already demonstrated resistance to the treatment with an SSRI. Applicant further argues that one would not treat PMS by treating only one possible symptom (depression).

This is not persuasive because, at the outset, Applicant is reminded that if a patient did not respond to a particular SSRI, it would have been obvious to one of ordinary skill in the art to administer another SSRI with the same reasonable expectation of successfully treating PMS. This is corroborated by the fact that, although the function remains the same, there is no one core structure associated with SSRI, as there are many structurally different classes of drugs that can be called SSRIs. It is well known that drugs even in the same class have varying degrees of bioavailability as a result structural differences. Although the mechanism of action may be the same, however bioavailability is a separate issue from the mechanism of action.

Furthermore, in applicant's own admission, the specification discloses that clinical studies on depression and anxiety disorders indicate that non-response or resistance to SSRIs, where at least 40-60% reduction in symptoms has not been achieved during the first 6 weeks of treatment (pg. 1, paragraph 3). Therefore, it would have been obvious to administer another SSRI, such as escitalopram, with a reasonable expectation of success in treating PMS. The skilled artisan does not simply give up a particular treatment regimen (class of drugs) if the initial drug is unsuccessful. The skilled artisan tries multiple times with a particular class of drugs before deeming this method a complete failure.

Examiner is not suggesting that one would treat PMS by treating only one possible symptom, such as depression. Boegesoe et al. clearly discloses the method of treating depression in a patient with escitalopram, an SSRI. Norden et al. clearly teach that SSRIs are useful in treating PMS. The Merck Manual was only used to corroborate the rejection by showing that depression is a symptom of PMS.

Applicant's arguments directed to the attached Zamorski article is not commensurate with the scope of the claims because the article discusses treating patients suffering from panic disorder that fail initial treatment with SSRIs, whereas the instant invention pertains to treating PMS. Nonetheless, nowhere in the Zamorski article does it preclude administration of another SSRI, no matter whether or not the patient has had at least a partial response to the first SSRI.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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